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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,387	12/02/1999	Thea A Wilkins	23070-095600	2583

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/453,387

Applicant(s)

WILKINS, THEA A

Examiner

Stuart Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 13-26 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,14,16 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7-11, 15, and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed June 27, 2002 has been entered.

Claims 1-26 are pending.

Claims 2 and 12 have been canceled.

This application contains claims 4, 6, 14, 16, and 21-26 are drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 4, 6, 14, 16, and 21-26 are withdrawn from consideration because they are drawn to non-elected material.

Claims 1 and 11 have been amended.

Claims 1, 3, 5, 7-11, 13, 15, and 17- 20 are examined.

2. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

3. Claims 1, 3, 5, 7-11, 15, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated *Gossypium hirsutum* cDNA GhMYB1 of SEQ ID NO:1 encoding SEQ ID NO:2 and *Arabidopsis* and tobacco transformation therewith, to obtain tobacco plants with 1) leaf margins and leaf veins bordered by elongated turgid, "waxy-looking" cells, 2) localized increase in density and to some

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degree increase in length of multicellular trichomes, 3) a notable increase in the basal cell of multicellular trichomes, 4) an increase in the number and density of small, glandular trichomes relative to the untransformed control and 5) a “ballooning” of epidermal cells in an undulating pattern on the surface of the leaf and a proliferation of adventitious roots and an increase in the distribution, number and length of root hairs, does not reasonably provide enablement for claims broadly drawn to any recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide encoding a MYB nucleotide sequence of at least 30 nucleotides in length or a MYB polynucleotide comprising a sequence at least 80% identical to SEQ ID NO:1 wherein the expression cassette is used in a method of modulating transcription in a plant and the MYB is expressed in cotton fibers or drawn to plant transformation with the exemplified or non-exemplified genes for obtaining a plant with alterations of root hairs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/21/02. Applicant’s arguments have been fully considered but they are not persuasive.

The Applicant asserts that MYB transcription factors have highly conserved domains that a skilled practitioner would be able to identify and use in the claimed invention. Applicant describes the conserved regions from the MYB transcription factors that are claimed in the present application (page 3-page 4, part A) which include a R2/R3 repeat, a tryptophan hydrophobic core and conserved DNA base-contacting residues. The Applicant then goes on to describe the characteristics that are measured in regards to cotton fibers (page 4-page 5, part B) which include fiber length, fiber strength and fineness. Lastly, Applicant contends that

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identification of MYB genes other than SEQ ID NO:1 does not require undue experimentation (page 5-page 6, part C) because now the claims are drawn to sequences exhibiting at least 80% sequence identity to SEQ ID NO:1 and that the present application teaches which positions are conserved and therefore which positions are critical for the function of the MYB polypeptides.

The Examiner agrees that MYB transcription factors possess certain conserved domains which include an amino-terminal DNA binding domain consisting of two or three helix-turn-helix motifs of 51-52 amino acids (R1, R2, and R3) and a transactivation domain (page 4 of the specification). It is these domains which classify proteins into the MYB family of transcription factors and not in some other group like the homeodomain transcription factor family. Just because a transcription factor possesses these domains does not mean that it will produce the desired result when transformed into a plant. Aside from these characteristic domains, the MYB transcription factor will possess other domains or other sequence motifs that permit or allow it to function in its characteristic way so that a particular process is carried out. If this were not the case, then all MYB transcription factors could be interchangeable in regards to other distinct processes, which they are not. The Applicant also discloses (see Loguercio et al., 1999, Mol. Gen. Genet. 261:660-671) that the TRR region (transcriptional regulatory region) which is located downstream of the DNA binding domain "varies considerably in both length and amino acid composition in a MYB-specific manner, even within a given species" and later they disclose that "each GhMYB TRR is unique" (page 644, left column, end of middle paragraph). Given that the Applicant has not identified the other regions or other amino acids that are required for the proper function of the cotton fiber MYB transcription factors, one skilled in the art would not be able to identify by sequence alone transcription factors (i.e., one that exhibit at least 80%

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sequence identity to SEQ ID NO:1) that would produce the expected result or produce any result in regards to modifying transcription, when transformed into a plant, let alone a cotton plant. It would still require undue experimentation to make and/or use the claimed invention.

4. Claims 1, 7-11, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of modulating transcription in a plant and a recombinant expression cassette both of which comprise a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1 and wherein the promoter directs expression in cotton fibers and root hairs. The claims are also drawn to a plant or a cotton plant comprising said recombinant expression cassette.

The Applicant isolated the invention from developing ovules of *Gossypium hirsutum* L. cv Acala SJ-2. The G11 gene was initially used to screen the corresponding cDNA library which yielded the MYB clone GhMYB1 (SEQ ID NO:1) whose sequence was analyzed and compared to 38 other plant MYB protein sequences. The Applicant does not identify structural features unique to the cotton GhMYB1 protein, nor the functional domains of the protein. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of

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an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for the cotton GhMYB1 gene of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2, it remains unclear what features identify a cotton GhMYB1 protein, including a cotton GhMYB1 gene with 80% homology to SEQ ID NO:1. Since a cotton GhMYB1 gene has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

5. The rejection of claims 1, 10-11 and 18-19 under 35, U.S.C. 102(b) is withdrawn based on Applicant's amendment and arguments.

6. The rejection of claims 1, 3, 7-11 and 17-20 under 35, U.S.C. 102(f) is withdrawn based on Applicant's amendment and arguments.

7. Claims 1, 3, 5, 9-11, 13, 15 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wada et al (1997, Science 277:1113-1116) taken with Wilkins et al (1993, NCBI Accession number L04497). This rejection is maintained for the reasons of record set forth in the Official action mailed 3/21/02. Applicant's arguments have been fully considered but they are not persuasive.

The Applicant contends that a *prima facie* case of obviousness has not been established for the following three reasons: 1) there is no suggestion or motivation to modify the references;

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2) there is no reasonable expectation of success; and 3) the cited art references do not teach or suggest all the claim limitations. The Applicant asserts that the Wada et al reference only hypothesizes that the isolated nucleic acid encodes a MYB-like protein and said reference as well as the NCBI publication do not teach that SEQ ID NO:1 or sequences 80% identical to SEQ ID NO:1 can be used to modulate transcription. In addition, Applicant asserts that “both references are silent as to the use of SEQ ID NO:1 to modulate plant transcription” (page 11, 4th paragraph). And lastly, Applicant asserts that “neither publication teaches or suggest a method of modulating transcription in a plant using a sequence at least 80% identical to SEQ ID NO:1” (page 12, 1st paragraph).

The Examiner disagrees with the Applicant. The Wada et al reference not only hypothesizes that the CAPRICE (CPC) gene is involved in trichome development, but they demonstrate this fact by over-expressing the CPC gene in *Arabidopsis* which produced plants with ectopic root hairs. This demonstrates that the CPC gene modifies transcription. It is true that the Wada et al reference does not explicitly state that using a sequence exhibiting at least 80% sequence identity to SEQ ID NO:1 will modulate transcription in a plant. But rather, what is demonstrated in their paper is that not only will sequences exhibiting at least 80% sequence identity to SEQ ID NO:1 modulate transcription when over-expressed in a plant, but there is a high probability that all MYB transcription factors will modify transcription when over-expressed in a plant. In addition, the NCBI reference discloses a sequence with MYB domains, and as Applicant has stated in the specification, (page 4) proteins that possess domains characteristic of MYB proteins can be expected to work as a MYB protein, and as such, can be used to modify transcription. Lastly, the Wada et al reference use a MYB protein to modify

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development of root hairs which are a type of trichome. Cotton fibers are a type of trichome.

Given that root hairs and cotton fibers are members of the same type of morphological structure, it would be expected that a transcription factor that affects development of one type of trichome will most likely affect the development of another type of trichome. It is clear to this Examiner that the motivation and expectation for success is apparent from the teachings of both the Wada et al and NCBI references.

8. Claims 3, 5, 13, and 15 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2.

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Sonya Williams, whose telephone number is (703) 305-2272.

Stuart Baum Ph.D.

September 23, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800